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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,750	01/16/2001	Ichiro Azuma	0020-4802P	7730

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,750	AZUMA ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,11 and 13-26* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-8,11 and 13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed July 13, 2004. Claims 21-25 have been amended. Claim 26 has been added. Claims 4, 9 and 12 have been cancelled. Applicant's submission of the declarations (by Dr. Kawabe and Dr. Nomura) filed under 37 CFR 1.132 are acknowledged.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Restriction

3. Applicant's elected Group IV, claims 21-25 with traverse in response filed November 3, 2003. The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, Groups are drawn to distinct products and methods capable of separate manufacture, use or sale. The Groups of inventions are independent and distinct based on the reasons given in the restriction requirement mailed October 3, 2003. Clearly different searches and issues are involved in the examination of each Group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Rejections Withdrawn

4. In view of Applicant's amendment the following rejections are withdrawn.

a) objection to the specification, page 2, paragraph 2.

b) objection to claim 21, page 2, paragraph 3 of the previous Office action.

c) objection to claim 25, pages 2-3, paragraph 4 of the previous Office action.

d) Rejection of claims 21-25 under 35 U.S.C. 112, second paragraph pages 3, paragraph 5.

e) Rejection of claims 21 and 22 under 35 U.S.C. 112, second paragraph pages 3, paragraph 6.

Rejections Maintained

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and newly submitted claim 26 for the reasons set forth on pages 4-6 paragraph 7 of the previous Office Action.

The rejection was on the grounds that Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent (see the Abstract). Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis* (column 2, lines 15-21). Yamamura et al teach the composition was prepared using suspending agents such as Tween and Span (surfactants) (column 2, lines 54-68). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property,

such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yamamura et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended and the properties of the claimed invention are defined in claim 21. Applicant urges that the Office misunderstands that the technical features of the present invention especially effects of "an organic solvent" used during the preparation of the emulsion. Applicant urges that an organic solvent is used to mix BCG-CWS and oil and then the organic solvent is evaporated off to given an intended emulsion. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent.

Applicant's arguments filed July 13, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil.

Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent. Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis*. Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided. Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

6. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and newly submitted claim 26 for the reasons set forth on pages 6-7 paragraph 8 of the previous Office Action.

The rejection was on the grounds that Cantrell teaches vaccines comprising cell wall skeleton which is obtained from microorganisms including *Nocardia rubra* and *Mycobacterium bovis* (column 4, lines 54-68) and squalene (oil). Cantrell teaches that the oil is combined with a detergent (i.e. Tween or Arlacel) (surfactant) (column 7, lines 27-35). Cantrell teaches the formation of oil droplet emulsions (column 7, lines 35-40 and column 10). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Cantrell anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended and the properties of the claimed invention are defined in claim 21. Applicant urges that the Office misunderstands that the technical features of the present invention especially effects of "an organic solvent" used during the preparation of the emulsion. Applicant urges that an organic solvent is used to mix BCG-CWS and oil and then the organic solvent is evaporated off to given an intended emulsion. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent.

Applicant's arguments filed July 13, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent. Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis*. Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to

prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided. Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

7. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and newly submitted claim 26 for the reasons set forth on pages 6-7 paragraph 8 of the previous Office Action.

The rejection was on the grounds that Yarkoni et al teach oil-in-water emulsions comprising *Mycobacterium bovis* BCG cell walls, squalane and Tween (surfactant) (page 881). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising

cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yarkoni et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Applicant urges that the claims have been amended and the properties of the claimed invention are defined in claim 21. Applicant urges that the Office misunderstands that the technical features of the present invention especially effects of "an organic solvent" used during the preparation of the emulsion. Applicant urges that an organic solvent is used to mix BCG-CWS and oil and then the organic solvent is evaporated off to given an intended emulsion. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the BCG-CWS without the use of a solvent.

Applicant's arguments filed July 13, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations

in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent. Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis*. Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided.

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method preparing an emulsion.

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

8. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and newly submitted claim 26 for the reasons set forth on pages 4-6 paragraph 7 of the previous Office Action.

The rejection was on the grounds that Van Nest et al teach compositions (oil-in-water emulsions) comprising bacterial components, oils, emulsifying agents (dispersion-aiding solvent), detergents (surfactants) in the form of oil droplets (see the Abstract). Van Nest et al teach that the composition of the invention comprise cell wall skeleton from *Mycobacteria* (column 9, lines 8-15). Van Nest et al teach that the oils used in the composition include squalene (column 4, lines 45-48). Van Nest et al teach that emulsifying agents include in the composition include ethanol (column 10, lines 58-63). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Van Nest et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended and the properties of the claimed invention are defined in claim 21. Applicant urges that the Office misunderstands that the technical features of the present invention especially effects of "an organic solvent" used during the preparation of the emulsion. Applicant urges that an organic solvent is used to mix BCG-CWS and oil and then the organic solvent is evaporated off to given an intended emulsion. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent and preparing the BCG-CWS without the use of a solvent.

Applicant's arguments filed July 13, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent. Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis*. Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-

CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided. Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 10).

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion not a method of preparing an emulsion.

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 21-25 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites "obtain by". It is unclear as to what Applicant is referring? Clarification is required.

10. Claims 21-25 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is not antecedent basis for "the oil droplets" in claim 21. Correction is required.

Status of Claims

11. No claims allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VLF

Vanessa L. Ford
Biotechnology Patent Examiner
September 29, 2004

LRS

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